

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference BCS 04-5003 PCT		FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/EP2005/002457		International filing date (day/month/year) 04.03.2005	Priority date (day/month/year) 05.03.2004	
International Patent Classification (IPC) or national classification and IPC C12N15/82, A01H5/00, A01H5/04				
Applicant BAYER CROPSCIENCE GMBH et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 21.12.2005		Date of completion of this report 24.01.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Bucka, A Telephone No. +31 70 340-		



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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-118 as originally filed

Sequence listings part of the description, Pages

1-91 as originally filed

Claims, Numbers

1-40 as originally filed

Drawings, Sheets

1/5-5/5 as originally filed

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify):*
- ☐ any table(s) related to sequence listing *(specify):*

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify):*
- ☐ any table(s) related to sequence listing *(specify):*

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-21,23-25,32-40
	No: Claims	22,26-31
Inventive step (IS)	Yes: Claims	1-21,23-25,32-40
	No: Claims	22,26-31
Industrial applicability (IA)	Yes: Claims	1-40
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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Supplemental Box relating to Sequence Listing

Continuation of Box I, item 2:

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☒ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment on
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional observations, if necessary:

Reference is made to the following documents:

- D1: WO 02/34923 A (AVENTIS CROPSOURCE GMBH; BAYER CROPSOURCE GMBH) 2 May 2002
D2: WO 96/27674 A (INSTITUT FUER GENBIOLOGISCHE FORSCHUNG BERLIN GMBH; KOSSMANN, JENS; SP) 12 September 1996
D3: MIKKELSEN RENE ET AL: "Functional characterization of alpha-glucan, water dikinase, the starch phosphorylating enzyme." BIOCHEMICAL JOURNAL, vol. 377, no. 2, 15 January 2004, pages 525-532, XP002339213

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1 The subject matter of **claims 22 and 26 to 31** cannot be considered to be new within the meaning of Article 33(2) PCT, since starch, which has been phosphorylated, has been described in the prior art (cf. D1, example 3; D2, example 4). The starch described in these documents cannot be distinguished from the starch described in the present application.
- According to the PCT Guidelines, A5.26[1], claims for products defined in terms of a process of manufacture are to be construed as claims to the product as such. A product is not rendered novel merely by the fact that it is produced by means of a new process. In the present case, the product as such, i. e. phosphorylated starch, is not new.
- 2 The subject matter of present **claim 1** relates to plants, in which the activity of two enzymes, which phosphorylate starch, has been increased. This should allow the *in planta* production of starch with advantageous characteristics.
- Document D1, which is considered to be the closest prior art, describes plants, in which one of such starch phosphorylating enzymes, called R1 or glucan, water

dikinase (GWD), is overexpressed, from which the subject matter of present claim 1 differs in that it also requires the overexpression of a starch phosphorylating enzyme, the so-called OK1 or phospho-glucan, water dikinase (PWD).

The problem to be solved by the present application is considered to be the provision of a further method to influence the phosphorus content of plant starch.

The solution proposed by the present application, which consists of the overexpression of two different starch phosphorylating enzymes, is considered to be the result of an inventive step. The closest prior art merely discloses one protein with the activity to phosphorylate starch.

Although there has been an indication in the state of the art that further similar enzymes exist in *Arabidopsis* (cf. D3, figure 7), there has been no suggestion that these proteins would have different activities, for instance in terms of their substrate preferences, i. e. glucan for GWD versus phospho-glucan for PWD. In addition, the present application shows that the second enzyme activity preferentially acts on a different C-atom than the previously known starch phosphorylating activities. For these reasons, the subject matter of present **claims 1 to 21, 23 to 25 and 32 to 40** is considered to meet the requirements of Article 33(3) PCT.

- 3 The terms "OK1" and "R1" used throughout the claims are arbitrary terms without a clear and unambiguous meaning in the state of the art. R1, for example, has now been replaced by the term glucan, water dikinase (cf. D3). These terms should be substituted by a clear reference to the enzymatic activity of the described proteins (cf. description, pages 8, 10).
- 4 The subject matter of **claim 1** is sufficiently supported and enabled by the description only in so far as it concerns the increase of the activity of these two starch phosphorylating enzymes by the introduction into plants of nucleic acids encoding these two enzymes. By way of example, the other theoretical possibilities mentioned in the description, e. g. by mutagenesis (cf. page 21), are neither sufficiently disclosed nor described in a manner that would allow the skilled person to carry out such a method.

Hence, in order to fulfil the requirement of Article 6 PCT that the claims shall define

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the invention, it appears to be necessary to introduce these essential technical features, for instance as recited in claim 5, into claim 1.

The same objection applies *mutatis mutandis* to **claim 15**.

- 5 The attention of the applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 34(2)(b) PCT).